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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,826	01/04/2001	Mohamed E. El Halawani	600.492US1	3468

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/754,826	**Applicant(s)** EL HALAWANI ET AL.	
	Examiner Michail A. Belyavskyi	**Art Unit** 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 May 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: 3.
   Claim(s) objected to: 30.
   Claim(s) rejected: 1,2,5-8 and 29.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

1. Claim 1-2 , 6-8 and 29 stand rejected under 35 U.S.C. 102(e) as being anticipated by Barker et al.(US. Pat. No. 6,369,201, see entire document) for the same reasons set forth in the previous Office Action, mailed 01/28/05.

Applicant's arguments, filed 05/02/05 have been fully considered, but have not been found convincing.

Applicant asserts that : (i) Barker et al. do not teach or suggest claimed immunoconjugate, because the body weights for the group treated with a recombinant myostatin immunoconjugate were not significantly different from the body weights in control groups i.e. the reconstituted myostatin immunoconjugate did not elicit an immune response; (ii) Barker et al., provide no assurance that a myostatin immunogen that is not a peptide would have any effect, much less that a mature myostatin can alter the phenotype of an immunized animal. Moreover, Barker et al. do not specifically mention the mature form of myostatin.

Contrary to Applicant's assertion Barker et al., teach mature forms of vertebrate myostatin, wherein vertebrate myostatin is an avian myostatin, and myostatin immunoconjugate comprising at least one myostatin polypeptide linked to an immunological carrier . (see entire document, colum 3, lines 25-40, Column 4, especially lines 1-4; column 7 lines 15-22, column 9, lines 22-35). It is noted that the instant specification define mature form of myostatin as a full length protein (see page 4 of the instant specification in particular). Barker et al., teach a full vertebrate myostatin polypeptide for example turkey myostatin (SEQ ID NO:35) that is a full length polypeptide of 375 amino acid. (See Fig.1 and column 4 in particular). In Detailed Description, Barker et al. teach that the term "myostatin immunogen" includes polypeptide of myostatin molecule, which elicits an immunological response (see column 6, lines14-25, column 15 lines 1-5, and column 16, lines 42-45). In addition, Barker et al., explicitly teach that administration of a myostatin immunoconjugate results in an increase in body weight (see column 4, lines 15-35 in particular). Moreover, Applicant himself acknowledge that , Barker et al. disclosed a myostatin immunoconjugates capable of eliciting an immune response in a vertebrate subject (see page 4of Applicant's arguments, 12/29/03 in particular). Barker et al. also teach vaccine composition comprising the myostatin immunoconjugate and pharmaceutically acceptable excipient (Column 4, line 10-15 and column 9, lines 35-50 and column 13, lines 1-65 in particular). In Detailed Description, Barker et al. teach that myostatin molecule is administrated in the mix with a pharmaceutically acceptable excipient, such as water, saline, dextrose , glycerol, ethanol. (Column 23, lines 45-65).

Barker et al. also teach that to enhance immunogenicity of myostatin, myostatin immunoconjugate which comprises a fusion polypeptide can be used. (see Column 10, lines 5-10 in particular).

The reference teaching anticipates the claimed invention

2. Claims 1 and 5 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al.(US. Pat. No. 6,369,201) in view of Harris et al. (Micron 1999, 30, 597-623) for the same reasons set forth in the previous Office Action, mailed 01/28/05.

Applicant's arguments, filed 05/02/05 have been fully considered, but have not been found convincing.

Applicant asserts neither Barker et al. nor Harris et al. disclosed or suggest a myostatin immunoconjugate, comprising the mature form of vertebrate myostatin linked to the carrier.

Contrary to Applicant's assertion, as has been discussed above, it is the Examiner position that Barker et al. teach mature forms of vertebrate myostatin polypeptide and myostatin immunoconjugate comprising at least one myostatin polypeptide linked to an immunological carrier . (see entire document, column 3, lines 25-40, Column 4, especially lines 1-4; column 7 lines 15-22, column 9, lines 22-35). Berker at al. further teach that immunological carrier can be any molecule which, when associated with a myostatin immunogen, enhances the immunogenicity of the molecule. (Column 9, lines 22-34).

Barker et al. do not explicitly teach that the carrier is KLH.

However, Harris et al. teach the widespread use of KLH as a hapten carrier and generalized vaccine component that is widely used to enhances the immunogenicity of the vaccine (see Abstract and entire document).

Given the teaching of Harris et al. that KLH is widely used as a carrier to enhance the immunogenicity of the vaccine, one of ordinary skill in the art would have find it obvious to modify the teaching of Barker et al. and substitute carrier described by Barker et al. for KLH carrier to enhances the immunogenicity of myostatin immunoconjugate. One of ordinary skill in the art at the time the invention was made would be motivated to substitute immunological carrier, described by Barker et al. for KLH carrier to enhances the immunogenicity of myostatin immunoconjugate. Finally, given the art recognize widespread use of KLH as a carrier to enhance the immunogenicity, one ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success to generate a myostatin immunoconjugate, comprising a myostatin polypeptide linked to KLH as a carrier.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.
Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

3. Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. The prior art does not teach or suggest the claimed invention as recited in claim 3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 10, 2005

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